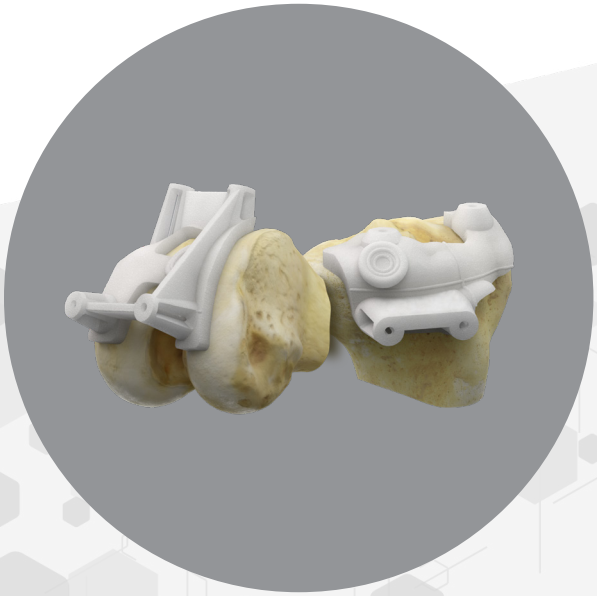
MRI SCAN PROTOCOL

Patient-Specific Knee Guides

BKS® Total PSI



ORTHO DEVELOPMENT®

powered by materialise

Purpose and Summary

This scanning protocol has been designed to obtain correct MRI images with an optimal quality that will be further used to design our patient-specific surgical guides. Materialise cannot be held liable for other possible subsequent uses (i.e. diagnostic uses).

The MRI scanning protocol is created to obtain all relevant clinical data of the anatomical structures of the patient's knee, as well as the overall alignment of the entire limb. The resulting scans of this sequence will be used to create 3-dimensional virtual anatomical models, a personalized surgical plan and surgical guides of the patient's knee prior to knee arthroplasty surgery.

Contact Materialise for Support

US: 1-734-259-6669
Europe: +32 16 98 04 88
Asia-Pacific: +603-7724-1418

General Scan Requirements

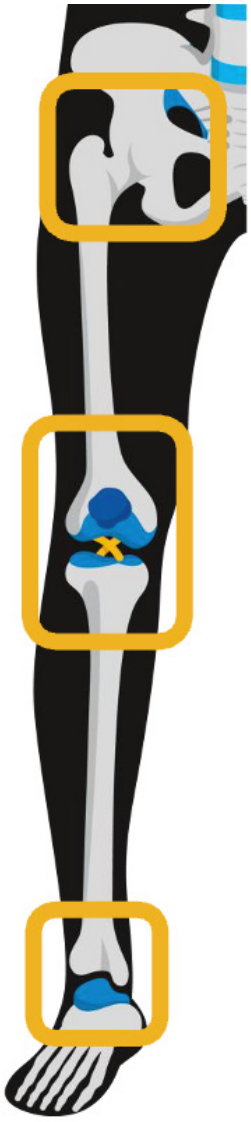
- This protocol is intended for 1.0 Tesla scanners or higher.
- The following systems are not supported: Siemens scanners with Numaris VA25 2004 software versions or Philips scanners with Picker software versions. These systems cannot provide the necessary coordinates data and/or imaging sequences for surgical planning.

Patient Preparation

- Discuss the procedure with the patient to ensure they understand the table will move during scanning.
- The patient must not move during any part of the scanning sequence. Patient movement will alter the relative alignment of the joints and invalidate the scan.
- Position the patient to maximize comfort and minimize motion. Use straps, sandbags, and sponges as needed to immobilize the patient.
- The knee of interest should be as close to center of the table, from right to left, as possible.
- As long as the knee remains in ISO-center and the knee coil is properly placed, the knee can be flexed and/or rotated up to 20 degrees.
- Choose a coil appropriately sized for your patient. If your patient's knee does not fit in a knee coil, please use a torso or flex coil to acquire the images.

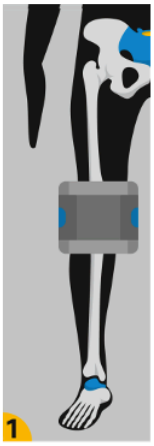
Imaging Guidelines

- For Siemens: Choose tablet position as “ISO” mode for all scans. Do not use “Scan at current table position” option in the older version of Syngo.
- The offsets defined in the following procedure are approximations only. Enter the table coordinates for each joint as precisely as possible; the actual offset will be based on the patient’s anatomy, not a default value.
- Multiple localizers can be used to locate the areas of interest as long as the patient is not re-positioned or re-landmarked. These localizers don’t need to be sent over along with the required images.
- Only true axial and sagittal slices will be accepted: NO OBLIQUE.
- The minimum scanning volumes required for each scan are as follows:
  - Axial ankle scan to cover the malleoli and talus
  - Sagittal knee scan(s) to cover the femoral condyles, tibial plateau and tuberosity
  - Axial hip scan to cover the femoral head and neck
- Use manufacturer’s defaults for parameters not listed.



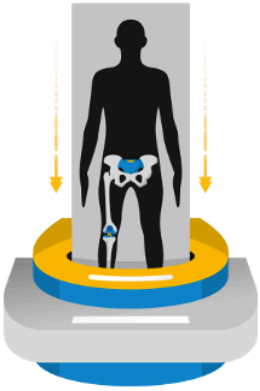
Preferred Scanning Procedure

This procedure consists of four series using 2 different landmarks: a high-resolution knee scan with a dedicated knee coil followed by a low-resolution series of the ankle, knee, and hip using the body coil only. It is compatible with all coil types, including Transmit-Receive coils, like the Invivo Hi Res Knee, 15-channel Knee or CP Extremity coils.



High-resolution knee scanned with a dedicated coil:

The high-resolution knee scan (with a dedicated coil in place) is used to capture a high-quality image of the knee for accurate 3D modeling of the knee. This scan should be performed first, to minimize the risk of patient motion. After this scan is complete, remove the coil and reposition the patient as necessary to prepare for the low-resolution series.



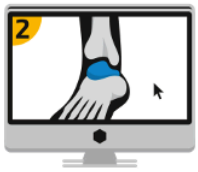
Low-resolution series of the ankle, knee, and hip; scanned with the body coil:

The low-resolution series is used to calculate the length of the femur and tibia, as well as the full alignment of the entire limb. This is done by tracking the table position/table coordinates of each separate joint scan. For this calculation to be accurate, re-landmarking must not be done during the low-resolution series. Additionally, the patient must not be moved, shifted, or repositioned in any way between the scans of the low- resolution series.

First, position the patient with the knee of interest as close to the center of the table as possible.

Then, place the dedicated knee coil and perform:

1. Hi-Res knee scan



Next, remove the coil and execute the Low-Res series of the lower limb.

2. Ankle scan
3. Knee scan
4. Hip scan

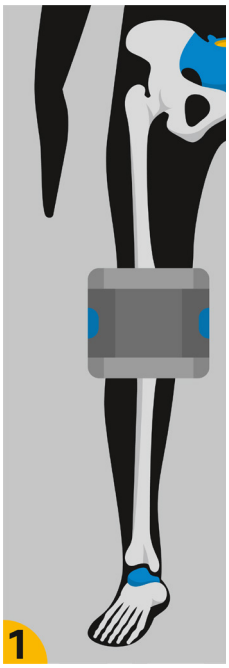
Finally, confirm the patient did not move during or in between scans.

Alternative Scanning Procedure

This procedure consists of one series with three consecutive imaging sequences; a high-resolution knee scan, a low-resolution ankle scan, and a low-resolution hip scan. It is only compatible with Receive-only coil types, like a Body Matrix, Body Array, or Flex coil. The use of a Receive-only coil makes it possible to scan without repositioning the patient for coil removal in between the ankle, knee, and hip scans.

High-resolution knee scanned with a dedicated coil:

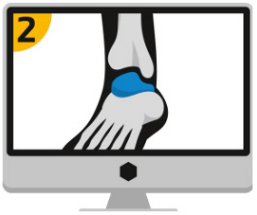
The high-resolution knee scan (with a dedicated coil in place) is used to capture a high-quality image of the knee for accurate 3D modeling of the knee and the surgical plan.



Low-resolution scans of the ankle and hip; scanned with the body coil:

The low-resolution series is used to calculate the lengths of the femur and tibia, as well as the full alignment of the entire limb. This is done by tracking the table position/table coordinates of each joint scan. For this calculation to be accurate, re-landmarking must not be done. Additionally, the patient must not be moved, shifted, or repositioned in any way between the scans of the series. Do not remove the knee coil used to acquire the knee series before scanning the ankle and hip.

First, position the patient with the knee of interest as close to the center of the table as possible.

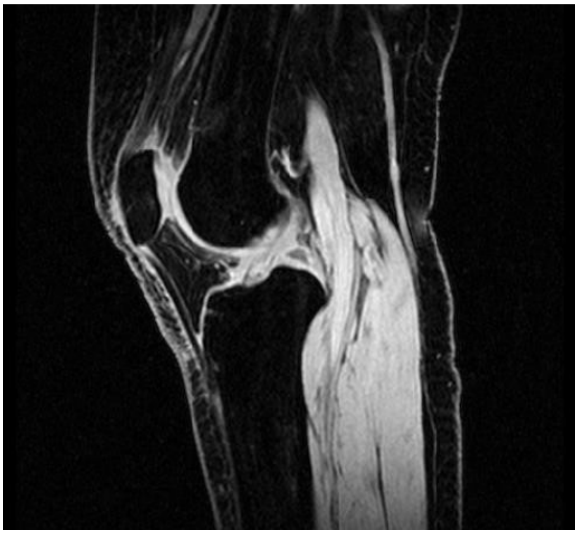


Then, place the dedicated coil and perform:

1. Hi-Res knee scan
2. Ankle scan
3. Hip scan

Finally, confirm the patient did not move during or in between scans.

1 High Resolution Knee Scan



Good signal is needed 100 mm above the knee joint and 100 mm below the knee joint, including visualization of the femoral condyles and tibia tuberosity.

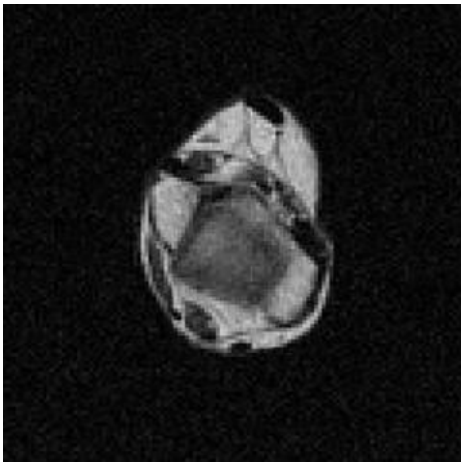
1. Position the patient on the table with the surgical side as close to ISO-center as possible.
2. Place the best fitting coil on the knee with the apex of the patella at the center of the coil.
3. Landmark at the center of the joint.
4. Scan knee localizers in true orthogonal planes.
5. Include SHIM scan.
6. Scan sagittal knee, including 10 cm of femur and 10 cm of tibia.
   - Slice thickness must be 1mm. Scan at 2mm and interpolate to 1mm if possible
   - Acquisition matrix is 256 x 256 with a reconstructed matrix of 512 x 512
   - Fat Saturation must be ON
   - TE should be shortest in-phase, TR should be T1 weighted
   - 1 concatenation
   - Phase FOV 80–100 percent; Phase Direction AP
   - Number of Averages should be 1 or 2
   - Do not use No Phase Wrap, Oversampling, or Fold Over Suppression
   - Do not use Half Fourier, Parallel Imaging, or filters unless indicated in table below
7. Enter the manufacturer-specific parameters as described in the table below; use manufacturer's defaults for parameters not listed.

Table 1: High-Resolution Knee Scan Parameters

	GE	Siemens	Philips	Toshiba	Hitachi
Slice Thickness	2mm with Zip 2 ON	1mm	2mm with Overcontiguous Slices ON	2mm with Fine ON	2mm with Recon Pitch Set to 1
Matrix	256x256 with Zip512 ON	256x256 with Interpolation ON	ACQ Matrix 256 x 256 with Reconstruction Matrix 512	Set PE Matrix to 256 with Fine ON	256x256 with Recon Matrix 512
Sequence	3D Vascular TOF Fast SPGR	3D WE Vibe	3D WATSc	3D FE3D	3D RSSG
TE	Min Full	Set Optimization to 'In Phase'	Set TE to Shortest 'In Phase'	TE Set at 5 for 1.5T and 3T	11.6 for 1.2T and 8.8 for 1.5T
Bandwidth	19.23 (1.5T) to 61 (3T)	130 (1.5T) to 260 (3T)	Non-Select	Non-Select	20-30
FOV	20-25 cm	200-250 mm	200-250 mm	20-25 cm	200-250 mm
TR	non-select	15-30	10-20	15-40	20-40
Flip Angle	10-25	10-25	10-25	10-25	10-30
Fat Saturation	ON- No Classic or Special	WE_Normal	Pro Set	Strong	Water Excitation, Wave 1-2-1
Scanner Specific	Do not use ZOOM	Use 2D/3D Distortion Correction	Technique T1-FFE		
		Use Excitation Slab-Select	Clear/ Sense is allowed		

- If following the preferred scanning procedure, remove the knee coil and reposition the patient for the low-resolution scans.
- If following the alternative scanning procedure, do not remove the knee coil or reposition the patient in any way.

2 Low-Resolution Ankle Scan



- If following the preferred scanning procedure, remove the knee coil and landmark at the malleoli of the ankle.
- If following the alternative scanning procedure, move table to scan the ankle using inferior offset ~300-400mm.
- Scanning bilateral ankles is not required.

1. Scan the ankle with the body coil only.
2. Acquire ankle localizer with true orthogonal planes.
3. Scan axial ankle from above the malleoli to the mid-calcaneus.
   - Fat Sat and Interpolation OFF
   - Number of Averages set to 1
   - TE should be in-phase, TR should be T1 weighted
   - 1 concatenation (this may require a TR in the PD weighted range)
4. Enter the manufacturer specific parameters as described in the table below; use manufacturer's defaults for parameters not listed.

Table 2: Ankle Scan Parameters

	GE	Siemens	Philips	Toshiba	Hitachi
Slice Thickness	5mm	5mm	5mm	5mm	5mm
Matrix	256x256	256x256	256x256	256x256	256x256
Sequence	2D TSE	2D TSE	2D TSE	FSE2D	2D FSE
TE	Min Full	4-20	20	10	8-12
Bandwidth	100-125	<500	Non-select	Non-select	30-60
FOV	26cm	260mm	260mm	26cm	260mm
Scanner Specific	Do not use ZOOM	Use 2D/3D Distortion Correction			

3 Low-Resolution Knee Scan *(Preferred Procedure Only)*

- If following the preferred scanning procedure, move table to scan the knee using superior offset ~300-400mm.
- If following the alternative scanning procedure, do not perform this scan.

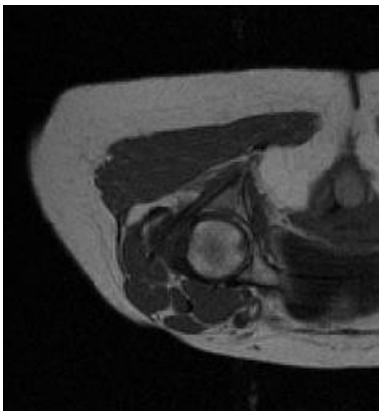
1. Scan the low-res knee with the body coil only.
2. Acquire knee localizers in true orthogonal planes.
3. Scan sagittal knee, including 10 cm of femur and 10 cm of tibia.
   - Fat Saturation must be ON
   - Phase FOV 80–100 percent; Phase Direction A/P
   - TE should be shortest in-phase, TR should be T1 weighted
   - 1 concatenation
   - Number of Averages should be 1 or 2
   - Do not use No Phase Wrap, Oversampling, or Fold Over Suppression
   - Do not use Half Fourier, Parallel Imaging, or filters unless indicated in table below
4. Enter the manufacturer specific-parameters as described in the table below; use manufacturer's defaults for parameters not listed.

Table 3: Low-Resolution Knee Scan Parameters

	GE	Siemens	Philips	Toshiba	Hitachi
Slice Thickness	5mm	5mm	5mm	5mm	5mm
Matrix	256x256	Set Base Resolution to 256	Set reconstruction matrix to 256	Set PE Matrix to 256	256x256
Sequence	3D Vascular TOF Fast SPGR	3D WE Vibe	3D WATSc	3D FE3D	3D RSSG

TE	Min Full	Set Optimization to 'In Phase'	Set TE to Shortest 'In Phase'	TE Set at 5 for 1.5T and 3T	11.6 for 1.2T and 8.8 for 1.5T
Bandwidth	19.23 (1.5T) to 61 (3T)	130 (1.5T) to 260 (3T)	Non-Select	Non-Select	20-30
FOV	26 cm	260 mm	260 mm	26 cm	260 mm
TR	Non-Select	18-25	10-20	15-40	20-40
Flip Angle	10-25	10-25	10-25	10-25	10-30
Fat Saturation	ON- No Classic or Special	WE_Normal	Pro Set	Strong	Water Excitation, Wave 1-2-1
Scanner Specific	Do not use ZOOM	Use 2D/3D Distortion Correction	Technique T1-FFE		
		Use Excitation Slab-Select	Clear/Sense is Allowed		

4 Hip Scan



- Move table to scan hip using superior offset ~300-400mm.
- Scanning bilateral hips is not required.

1. Scan the low-resolution hip with the body coil only.
2. Acquire hip localizer with true orthogonal planes.
3. Scan axial hip from anterior superior iliac spine to pubic symphysis.
   - Fat Sat and Interpolation OFF
   - Number of Averages set to 1
   - TE should be in-phase, TR should be T1 weighted
   - 1 concatenation (this may require a TR in the PD weighted range)
4. Enter the manufacturer specific parameters as described in the table below; use manufacturer's defaults for parameters not listed.

Table 4: Hip Scan Parameters

	GE	Siemens	Philips	Toshiba	Hitachi
Slice Thickness	5mm	5mm	5mm	5mm	5mm
Matrix	256x256	256x256	256x256	256x256	256x256
Sequence	2D TSE	2D TSE	2D TSE	FSE2D	2D FSE
TE	Min Full	4-20	20	10	8-12
Bandwidth	100-125	<500	Non-select	Non-select	30-60
FOV	36 cm	360 mm	360 mm	36 cm	360 mm
Scanner Specific	Do not use ZOOM	Use 2D/3D Distortion Correction			

Submitting the Images

- Only DICOM format will be accepted.
- No .jpg images or other formats are acceptable.
- Do not submit interpolated or reformatted images.
- Only original scan data is acceptable.
- Uncompressed Dicom data is required for processing.
- Lossy and other forms of compression are not recommended.
- The scanner should be set to DICOM format “raw image,” with no compression. If loading from PACs, import and export the scan as DICOM files with the uncompressed option.
- Scan data will be uploaded through SurgiCase Online using the Upload Plugin. Please see the SurgiCase Online User Guide for Scan Centers for further details.

Questions:

Contact Ortho Development Marketing Support
Phone: + 1 801.553.9991
Email: Materialise@orthodevelopment.com

BKS® Total PSI is powered by Materialise and distributed by Ortho Development.

351-I-10824 Rev 092022

We help people do what they love by restoring mobility.

For more information about Ortho Development products, please visit www.odev.com.

12187 S. Business Park Drive | Draper, Utah 84020 | 801.553.9991